**Supplementary material**

**Reference testing techniques**

The Fecobionics test and ARM-BET were done in random order, whatever was most convenient from a logistics point of view.

***ARM with BET*** was conducted with a standard single-use 8ch anorectal catheter (G-90150, MMS, Enschede, Netherlands). It was inserted with the subjects lying in left lateral position with bended hip and knees. The bag was placed in the rectum and pressure was measured at 0.5cm distance in the anal canal. Resting anal pressure, maximum anal squeeze pressure, the recto-anal inhibitory reflex (RAIR), urge volume, maximum tolerable volume, and expulsion duration for the 50ml balloon were evaluated. BET was done on the commode chair.

**Fecobionics Device description**

Fecobionics was 12-mm-OD, 10-cm-long and made of medical grade Silicone rubber (PS6600, Yipin Mould Material Ltd, China) with hardness shore A5. It contained the sensors and circuit boards including the Microprogrammed Control Unit.

A 30μm-thick and 8cm-long polyester-urethane bag spanned most of the core length. The spherically shaped bag contained up to 80 ml without being stretched and had a maximum diameter of 6cm. The bag was connected through a thin tube extending from the front of Fecobionics to a syringe containing saline.

Miniature pressure sensors (MS5837-30BA, TE connectivity, USA) were embedded at the front, inside the bag, and at the rear of the core. The front and rear sensors pointed in axial direction. Since the sensor measures absolute pressure, zero pressure reference adjustment at atmospheric pressure was done before measurements. The MPU6050 (InvenSense, USA) was used as the motion processor unit (MPU) to measure orientation. Bending of Fecobionics was computed from two MPUs placed towards the ends. Each MPU contained a triple axis accelerometer, triple axis gyroscope and Digital Motion Processor, which processes complex 6-axis motion algorithms. A complementary filter was designed to achieve a good dynamic response and to solve gyroscope drift problems12. Fecobionics was calibrated in a one-step procedure.

Four wires were threaded inside a thin tube extending from the front to the USB port of a computer for power supply and data transmission for real-time collection, computation, and display of data on the graphical user interface. Further processing was done in MATLAB. Validation data for the Fecobionics device have been published12.

Device safety was assessed during and after the procedures by feedback from the subjects studied as well as from the recorded data. The devices were inspected for leaks and damage or malfunction. Any safety issue and adverse effects were characterized and reported as unanticipated adverse device effects. The subjects were instructed in contacting a specific member of the research team if they experienced any problem after leaving the clinic.

**Data Analysis**

Advanced parameters and analyses comprised:

* Expulsion velocity computed as 10cm (length of the device) divided by the time difference between the expulsion of the front and rear of Fecobionics (time point when the pressure sensors first measured atmospheric pressure). Hence, the calculation spanned over the final expulsion contraction or several contractions.
* Five phases of defecation were defined from the pressure signals as illustrated in Figure 1B11.
* Front pressure as function of rear pressure as a proxy of preload-afterload conditions2,16,S1 (Figure 1C).
* Orientation of the motion sensors relative to the field of gravity and the angle between them. 180 degrees indicates that the device was straight. The bending angle was 180 degrees minus the measured angle.

**Technological and further methodological aspects**

According to the international ISO13485 medical device standard, Fecobionics is a low risk insertable device since it will reside inside a natural orifice of the human body for less than 1h. All materials in contact with mucosa were medical grade. Silicone was the ideal core material due to its softness, durability, non-degradability, electrical current insulation, and lack of chemicals suspected of having carcinogenic effects. The silicone core ensured that most electrical components were not in direct contact with tissue, which is important if batteries leak or the electronics short-circuits. The bag provides a double protection against leakage.

 The pressure sensors at the two ends pointed in axial direction, i.e. in the direction of the trajectory. This is a key design feature that is distinctly different from other anorectal pressure measurement devices such as high-resolution and high-definition ARM that measure radial pressuresS2,S3. The MPUs provided data on orientation and bending angle. Fecobionics can be developed further to encompass impedance planimetry that will allow measurement of shape changes during defecation and better estimates of the preload-after load properties and stress-strain properties2,S1. Developments are also ongoing for making Fecobionics wireless and battery-powered. Furthermore, the tube for filling the bag can be detached to avoid tethering after bag filling. The two ends of Fecobionics are named front and rear. These terms refer to which end is defecated first and last.

It is important to evaluate potential risks of new medical device innovations and the cost of producing the devices. For risk assessment we collected data on discomfort, symptoms, device malfunction, leakage and unanticipated adverse device effects. We did not discover problems in the 20 subjects, except for malfunctioning pressure sensors in a few cases. The cost of goods sold (COGS) was approximately US$100 and about 5hrs of work was spent on assembly and testing. The COGS is well below standard reimbursement rates for anorectal studies.

Fecobionics was developed in an attempt to integrate current tests and to provide a new bionics concept that will allow more physiological recordings. Current tests have been criticized for not reflecting defecatory physiology. BET, ARM, defecography, and dynamic pelvic MRI are indirect surrogates for the act of defecation, and provide incomplete and often conflicting information10. Not surprisingly, the results of these tests correlate poorly with symptoms and treatment outcomes. The simplest anorectal physiology test is the BET where an intrarectal balloon is filled with 50ml and the patient attempts to expel it. Expulsion within 1-2min is considered normalS4,17. BET suffers from the lack of physiological measurements such as pressure profiles, angle and geometric changes during anal passage. ARM records the pressure exerted by the anal sphincters and puborectalis during rest and contraction. Defecography shows how well the rectum holds and evacuates the stoolS5,S6 and provides important data on the anorectal angle, anal and rectal diameters and anatomic features such as rectoceles. Dynamic pelvic MRI (i.e., MRI defecography) is an alternative, which is better for some anorectal problems but not as good for othersS7. MRI defecography uses a liquid with mechanical properties that are quite dissimilar to feces and hence cannot represent the true signature of defecation. The problem with most tests is that they do not provide detailed physiological data during defecation, reflecting the dynamics of the defecation process. Hence, a new approach using innovative devices that can provide real time, quantitative, and mechanistic insights by simulating defecation through multi-dimensional measurements of pressure profiles, deformability, and topographic changes is warranted.

**Characteristics for the subjects excluded from the normal subject group**

The 68-years-old female with FI score 12 expelled the ARM-BET and Fecobionics bags in a few seconds and had a low anal sphincter pressure (Supplementary figure 1A). The pressure cycle was at all points below the line of unity (Supplementary figure 1B). The three subjects, who exceeded the 2min limit in ARM-BET were as follows: The subject who could not expel the ARM-BET, despite trying for up to 10min, also could not expel Fecobionics. It was noted prior to the experiments that the subject spent considerable time in the restroom trying to empty rectum. Afterwards the subject admitted symptoms of obstructed defecation and surgery for anal fistula two years earlier. Another subject used 134sec to expel the ARM-BET balloon and 210sec to expel Fecobionics (Supplementary figure 1CD). The third subject used 408sec to expel ARM-BET and 292sec to expel Fecobionics. This subject admitted taking medicine for chronic constipation and had a 2.5cm anterior rectocele. In brief, 100% agreement existed between ARM-BET and Fecobionics for categorizing defecations as normal or abnormal based on the 2min cut-off limit commonly used in BET studies.

**Supplementary Figure 1**

AB) Representative example of defecation from the subject with FI score 12. The FI patient had a low sphincter pressure and the rear pressure exceeded the front pressure during the entire evacuation. The arrows in the left diagram show the beginning of the five phases and in the right diagram the clockwise contraction loop. CD) Pressures and angle data from a subject that used many attempts and more than 2min to expel Fecobionics. The pressure difference towards the end increased which is primarily due to anal sphincter relaxation. Simultaneous changes in angles were observed.

**Supplementary References**

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